The ACA Medicaid Rebate Rule Change: Impact on Pricing and Innovation

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Motivation I: How do firms respond to government pricing & subsidies?

- Price regulation/subsidies are common in welfare programs
  - Medicare/Medicaid reimbursement
  - Premium subsidies for insurance plans
  - Rent control/public housing vouchers
  - Federal financial aid for colleges
  - Food stamps

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- Regulation leads to distortions
  - Government benchmarks can anchor private prices (e.g. Medicare reimbursement rates)
  - Fluctuating benchmarks that are tied to equilibrium prices will change firm strategic incentives

Motivation II: the Medicaid Drug Rebate Program

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- Cross-sectional evidence on list prices only
- MDRP contains provisions than DSM06 doesn't consider

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- MDRP contains provisions than DSM06 doesn't consider
- Medicaid has changed since 2006:
  - Medicare Part D covers dual eligibles
  - MDRP formula increased minimum rebate in 2010
  - New data on estimated net prices is available

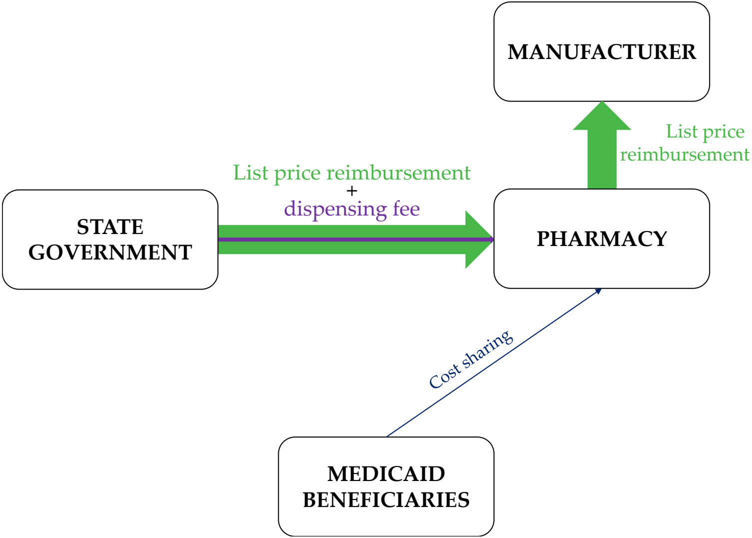
We find that the MDRP has a more nuanced impact than previously thought

Main takeways

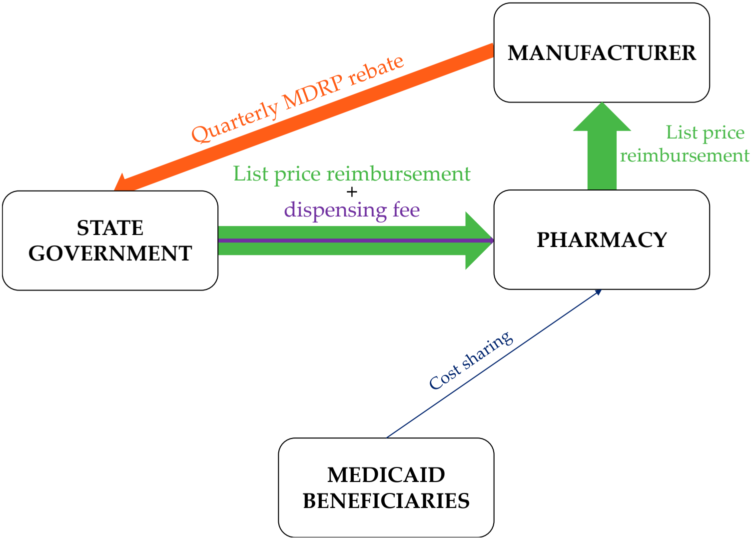
- Drugs with high Medicaid exposure:
  - Increase prices at a lower rate
  - Give lower commercial rebates
  - Launch line extensions at a higher rate
- (Not today): Little evidence of higher launch drug prices
- 2010 increase in minimum rebate enhanced positive/reduced negative effects

Overview of the Medicaid Drug Rebate Program

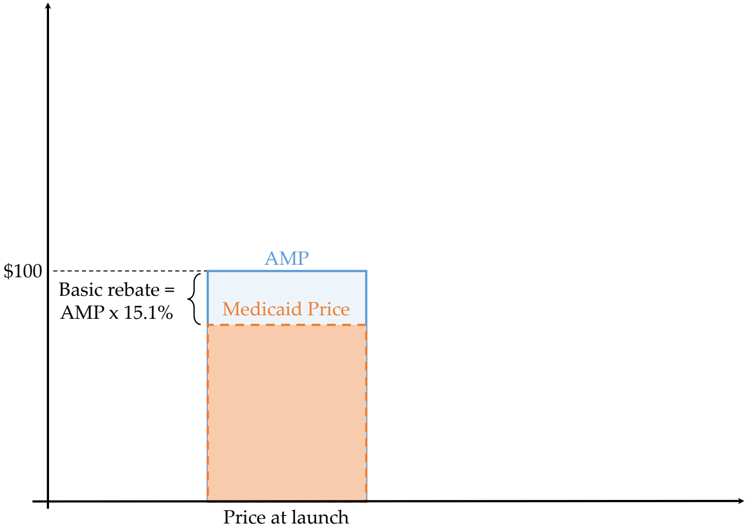
Medicaid initially pays for drugs at list prices



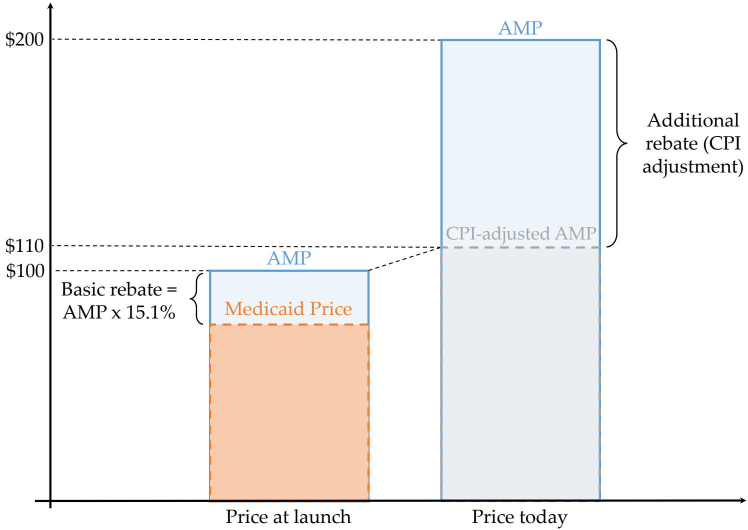
Manufacturers then send lump-sum rebates



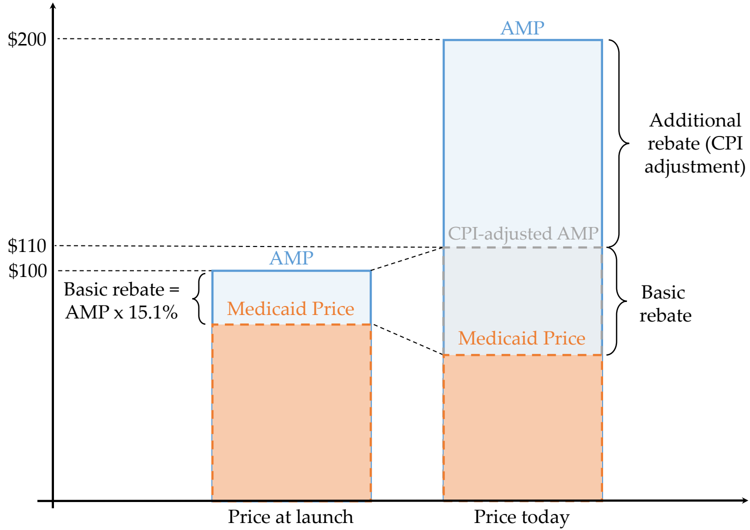
Quarterly rebate is a fraction of list price



Formula implies the price is anchored to launch price



And that prices fall if price growth exceeds inflation



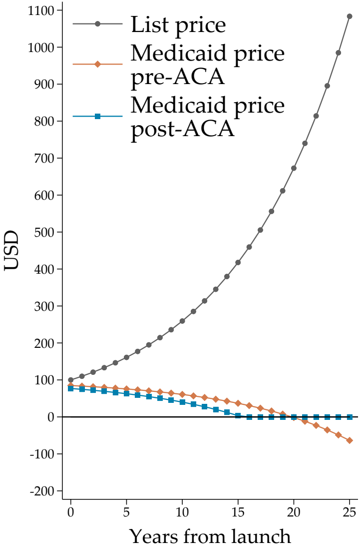
There are a few other relevant features of the program

- Medicaid is entitled to the "best price" if it is lower than $AMP - 15.1\%$
    - Difference between AMP and best price becomes new rebate %
    - Basically a "most-favored nation" clause
- Line extensions "reset the clock" on price
    - Line extensions are versions of the drug with the same active ingredient but different form/strength
    - Firms get to set a new initial price for line extensions

CMS changed the formula starting in January 2010

Two main changes:

- Base rebate increased from **15.1%** to **23.1%** of AMP
- Max rebate capped at **100%**



Optimal firm behavior

Setting

- Increasing demand
- Medicaid demand inelastic
- Maximum initial price bounded
- Firm sets AMP, discount
- Medicaid formula:

  $$p_t^{\text{Med}} = \min\left(p_0, p_t\right) - p_t \times \max\left(r, d_t\right)$$

  where
  - p_0 is the launch AMP
  - p_t is the AMP in period t
  - d_t is the discount granted to commercial payer

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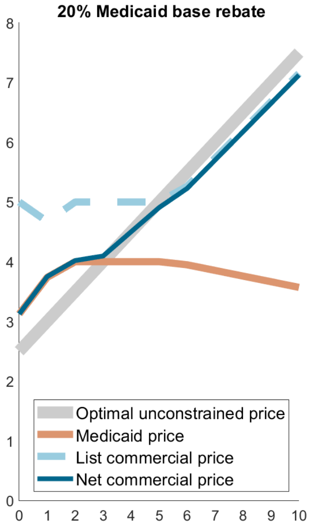

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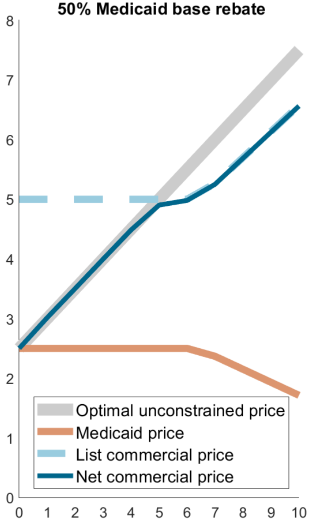

From the model we derive a few testable hypotheses

Drugs with high Medicaid exposure will have:

1. Slower list price growth (but possibly higher launch price)
2. Lower discounts to commercial payers (to avoid triggering the best-price clause)
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After the formula changes:

1. Even slower list price growth (unless discount is at 100%)
2. Higher-than-before discounts to commercial payers
3. Even higher probability of line extensions

Data and Empirical Strategy

Data

- SSR Health (~1,000 brand drugs, quarterly from 2007-2019)
    - Gross sales, volume
    - Net sales (obtained from SEC filings)
    - Product name level (e.g. ABILIFY)
- Medicaid PUF (quarterly from 1990-2019)
    - Gross sales, volume
    - NDC level (product-form-strength), e.g. ABILIFY-TABLET-20MG

Key variables

- **Medicaid Market Share**:

$$MMS = \frac{\text{Medicaid sales}}{\text{Invoice sales}}$$

- **List price**: measured as Wholesale Acquisition Cost (WAC)
- **non-Medicaid discount**: estimated as

$$1 - \frac{\text{Net sales} - \text{net Medicaid sales}}{\text{Invoice sales} - \text{Medicaid sales}}$$

- **Number of line extensions**: new NDC with new form or strength

Issue: invoice sales are underreported for many drugs

- Problem for many specialty, physician-administered drugs
- Example: Eylea (Aflibercept, macular degeneration)
  - WAC sales (2013): ~6 million
  - Medicaid sales: ~5 million

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- Problem for many specialty, physician-administered drugs
- Example: Eylea (Aflibercept, macular degeneration)
  - WAC sales (2013): ~6 million
  - Medicaid sales: ~5 million
  - Net sales: ~1.5 billion
- Solution: drop drugs with net sales > invoice sales over the life-cycle

Estimation exploits variation in exposure to Medicaid to estimate diff-in-diff around 2010

- Two independent variables of interest
  1. Medicaid Market Share $\rightarrow$ matters for price
  2. Medicaid sales $\rightarrow$ matters for line extensions
- Sample: drugs launched in 2007 w/ positive sales in 2009
- Two regression designs:
  1. Linear interaction of MMS/Sales with policy change
  2. Interaction of quartiles of MMS/sales with policy change

Results I: Price Distortions

List price of drugs with high MMS grows more slowly

$$log\left(WAC_{it}\right) = \alpha_i + \delta_t + \beta_1 \times MMS_i \times (t - 2007)$$

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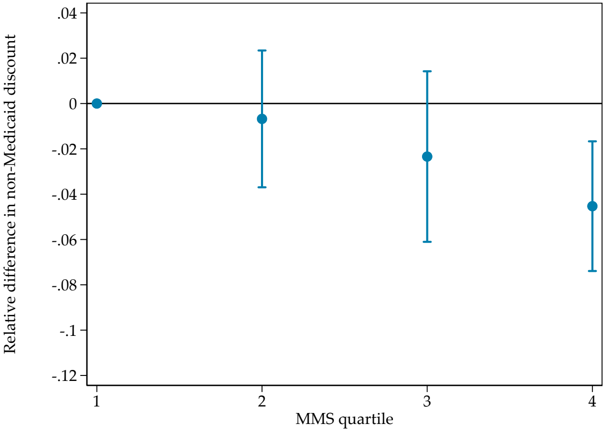
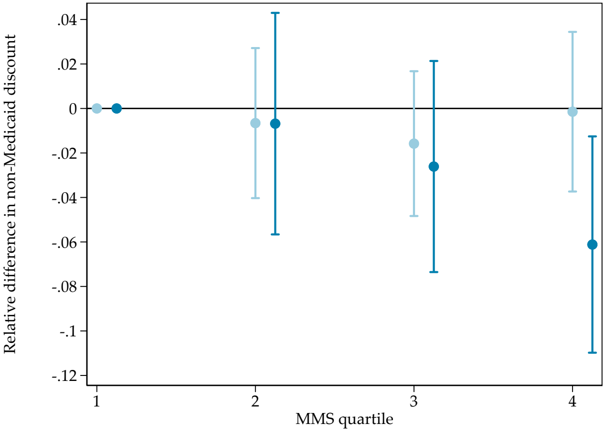


and even more slowly after 2010

$$
\begin{aligned}
log\left(WAC_{it}\right) = \alpha_i + \delta_t + \beta_1 \times MMS_i \times (t - 2007) \\
+\beta_2 \times MMS_i \times PostACA_t \times (t - 2010)
\end{aligned}
$$



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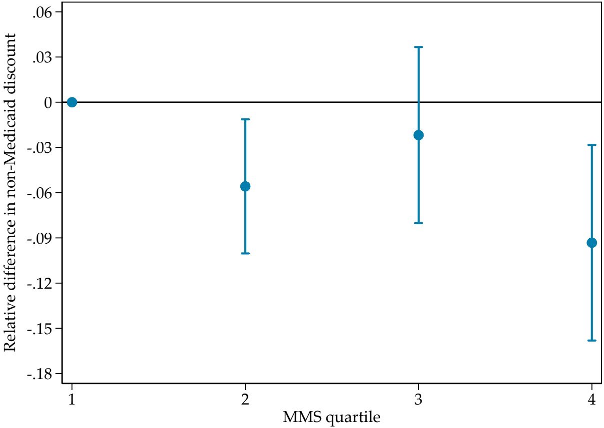
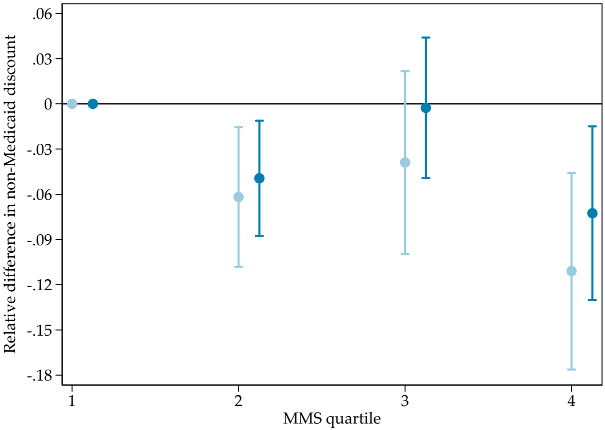


but less so after the change in the formula

$$Discount_{it} = \delta_t + \beta_1 \times MMS_i + \beta_2 \times MMS_i \times PostACA_t$$



Results II: Innovation Distortions

Line extensions are more likely for drugs with high Medicaid sales

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	All Line Extensions
High Med Sales	**2.278****
	(0.367)
Post-ACA	
High Med Sales $\times$Post-ACA	
N	552

and even more so after the ACA

$$\lambda\,(\text{age}|\,X) = \lambda_0\,(\text{age}) \times \exp\,(X)$$

	All Line Extensions	
High Med Sales	2.278**	1.725**
	(0.367)	(0.364)
Post-ACA		0.947
		(0.246)
High Med Sales $\times$Post-ACA		**2.078***
		(0.691)
N	552	552

Which line extensions are more profitable under Medicaid rules?

Intuition

- Key of a line extension is to get people to switch
- Higher quality line extensions can get more people to switch
- Marginal gain from extra switchers increases with base rebate

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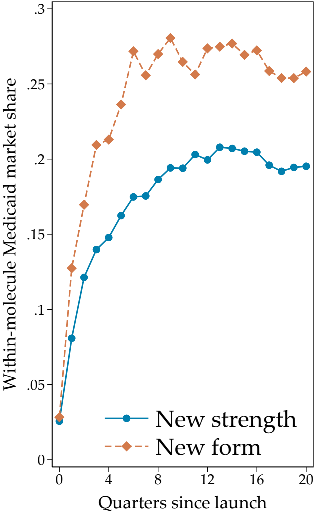

Firms develop higher-quality line extensions post-ACA

$$\lambda\left(\text{age}\middle|\, X\right) = \lambda_0\left(\text{age}\right) \times \exp\left(X\right)$$

	New Form		New Strength	
High Med Sales	2.459**	1.439	2.370**	1.939**
	(0.600)	(0.515)	(0.404)	(0.433)
Post-ACA		0.937		1.110
		(0.348)		(0.304)
High Med Sales		**3.029***		**1.697**
×Post-ACA		**(1.500)**		**(0.589)**
N	552	552	552	552

Conclusion

The Medicaid Drug Rebate Program affects pricing and R&D strategies of firms

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Predicting effect of policy change is not easy

- Simple prediction: $\uparrow$ mandatory rebate $\implies$ $\uparrow$ distortion
- But firms face a lot of constraints that are hard to model
- These constraints affect predictions
- In this case, the reform turns out to be relatively benign